DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95551

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

Certified Mail
Return Receipt Requested

WARNING LETTER

FLA-05-09

November 18, 2004

Felix Cabeza, President/Owner
La Dorada Coral Gables, Inc.
177 Giralda Avenue
Coral Gables, Florida 33134-5208

Dear Mr. Cabeza,

On August 23-24, 2004, the United States Food and Drug Administration (FDA) conducted an inspection your facility located at 177 Giralda Avenue, Coral Gables, Florida 33134-5208. The inspection was conducted to determine your firm's compliance with FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123).

During our inspection, the FDA investigator observed deviations from the seafood HACCP regulations. The FDA Investigator also provided your General Manager, Beatrice H. Bajares, with a copy of the form FDA 483, a copy of which is attached to this letter, which presents her evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health or have not been processed under insanitary conditions, to comply with 21 CFR 123.12 (a)(2)(i). However, your firm does not have product specifications for anchovies, sardines and sea bass imported from Spain.

2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for anchovies, sardines and sea bass manufactured by [redacted] in Spain.

These HACCP deviations that the FDA investigator found during the current inspection were the same deviations that FDA previously found during its August 21 and 24, 1998 inspection of your facility. FDA notified your firm of these prior deviations in our September 23, 1998, letter to Victor Passalacque, your previous General Manager, a copy of which is enclosed.

The above-listed deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and /or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific steps you have taken to correct these violations including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason or the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Virginia L. Meeks, Compliance Officer, 555 Winderley Place Suite, Maitland, FL 32571. If you have questions regarding any issue in this letter, please contact Ms. Meeks at (407) 475-4731. We look forward to working with you to achieve a successful HACCP program.

Sincerely,

Emma R. Singleton
Director, Florida District